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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stavrianopoulos et al.

Serial No. 08/486,070

Filed: June 7, 1995

Title: **SOLID SUPPORT COMPRISING AN ARRAY OF SUBSTRATE SURFACES FOR NUCLEIC ACID ANALYSES AND APPLICATIONS, AND OTHER COMPOSITIONS AND SYSTEMS EMPLOYING CHEMICALLY LABELED OLIGONUCLEOTIDES OR POLYNUCLEOTIDES (As Previously Amended)**

Group Art Unit: 1631

Ex'r: Ardin H. Marshel, Ph.D.

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527 Madison Avenue, 9th Floor
New York, New York 10022
May 1, 2001

FILED BY EXPRESS MAIL

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. §§1.56 & 1.97-1.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following seventy-nine (79) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

1. Leary, Brigati and Ward, "Rapid and sensitive colorimetric method for visualizing biotin-labeled DNA probes hybridized to DNA or RNA immobilized on nitrocellulose: Bio-blots," Proc. Natl. Acad. Sci (USA) 80: 4045-4049 (July 1983) (Exhibit 1);

2. DE-A-29 15 082, published October 31, 1979 (Exhibit 2);

3. Avrameas and Guilbert, "Enzyme-immunoassay for the measurement of antigens using peroxidase conjugates," Biochimie 54: 837-842 (1972) (Exhibit 3);

EXPRESS MAIL CERTIFICATE

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Deposit Date May 1, 2001
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.

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Date

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4. U.S. Patent No. 4,724,202, issued February 9, 1988 (Exhibit 4);

5. Buongiorno-Nardelli and Amaldi, "Autoradiographic Detection of Molecular Hybrids between rRNA and DNA in Tissue Sections," Nature 225: 946-948 (Exhibit 5);

6. Gall and Pardue, "Formation and Detection of RNA-DNA Hybrid Molecules in Cytological Preparations," Genetics 63: 378-383 (Exhibit 6);

7. John et al., "RNA-DNA Hybrids at the Cytological Level," Nature 223: 582-587 (1969) (Exhibit 7);

8. Ward et al., U.S. Patent No. 5,328,824, issued July 12, 1994 (Exhibit 8);

9. Ward et al., U.S. Patent No. 5,449,767, issued September 12, 1995 (Exhibit 9);

10. Engelhardt et al., U.S. Patent No. 5,260,433, issued November 9, 1993 (Exhibit 10);

11. Benton, W.D. and Davis, R.W., "Screening Agt recombinant clones by hybridization to single plaques in situ," Science 196: 180 (1977) (Exhibit 11);

12. Boguslaski et al., U.S. Patent 4,230,797, issued October 28, 1980 (Exhibit 12);

13. Boguslaski et al., U.S. Patent 4,261,893, issued April 14, 1981 (Exhibit 13);

14. Boguslaski et al., U.S. Patent 4,318,980, issued March 9, 1982 (Exhibit 14);

15. Boguslaski et al., U.S. Patent 4,380,580, issued April 19, 1983 (Exhibit 15);

16. Boguslaski et al., U.S. Patent 4,383,031, issued May 10, 1983 (Exhibit 16);

17. Burd et al., U.S. Patent 4,318,981, issued March 9, 1982 (Exhibit 17);

18. Hevey et al., U.S. Patent 4,228,237, issued October 14, 1980 (Exhibit 18);

19. Hornby et al., U.S. Patent 4,318,982, issued March 9, 1982 (Exhibit 19);

20. Litman et al., U.S. Patent 4,374,925, issued February 22, 1983 (Exhibit 20);

21. Ranki et al., U.S. 4,486,539, issued December 4, 1984 (Exhibit 21);

22. Self, U.S. Patent 4,446,231, issued May 1, 1984 (Exhibit 22);

23. Boguslaski et al., U.S. Patent 4,134,792, issued January 16, 1979 (Exhibit 23);

24. DE-A-2618419, published April 11, 1976 (Exhibit 24);

25. Boguslaski et al., UK Patent Application GB2026690, published February 6, 1980. (Exhibit 25);

26. Ward et al., U.S. Patent 5,476,928, issued December 19, 1995 (Exhibit 26);

27. Bauman et al., "Rapid and High Resolution Detection of in situ Hybridization to Polytene Chromosomes Using Fluorochrome-Labeled RNA." Chromosoma (Berl.) 84: 1-18 (1981) (Exhibit 27);

28. Bildwell et al., "Enzyme Immunoassays for Viral Diseases," J. Infectious Disease: 136: S274-S278 (1977) (Exhibit 28);

29. Broker et al., "Electron Microscopic Visualization of tRNA genes with Ferritin-Avidin: Biotin Labels," Nucl. Acids Res., 5(2): 363-384 (1978) (Exhibit 29);

30. Engvall and Perlmann,"Enzyme-linked immunosorbent assay (ELISA) Quantitative assay of immunoglobulin G," Immunochem 8: 871-874 (1971) (Exhibit 30);

31. Fertel R. and Weiss, B., Methods in Enzymol. Vol LV II, Bioluminescence and Chemiluminescnece, DeLuca, M.A. (Ed.) 94-106 (1978) (Exhibit 31);

32. Hamaguchi et al., "Enzyme-Linked Sandwich Immunoassay of Macromolecular Antigens Using the Rabbit Antibody-Coupled Glass Rod as a Solid Phase," Eur. J. Biochem. 7: 459-467 (1976) and FEBS Letters: 69(1): 11-14 (1976) (Exhibit 32);

33. Hofmann et al., "Iminobiotin Affinity Columns and Their Application to Retrieval of Streptavidin", Proc. Natl. Acad. Sci. USA, 77, No. 8, pp. 4666-68 (1980) (Exhibit 33);

34. Miranda, Q.R:, et al., "Solid-Phase Enzyme Immunoassay for Herpes Simplex Virus," J. Infectious Disease 136: S304-S310 (October, 1977) (Exhibit 34);

35. Langer and Ward, Abstract 1153: "A Rapid and Sensitive Immunological Method for In Situ Gene Mapping in Journal of Supramolecular Structure and Cellular Biology, (1981) (Exhibit 35);

36. Langer and Ward, "A Rapid and Sensitive Immunological Method for In Situ Gene Mapping," in Developmental Biology Using Purified Genes, ed. D.D. Brown, Academic Press, pp. 647-58 (1981) (Exhibit 36);

37. Mosback, K., et al., "immobilized Coenzymes," Methods in Enzymology, Vol. XLIV: 859-887 (1976) (Exhibit 37);

38. Nishimura et al. "Synthetic Nucleosides and Nucleotides: 5-Dimethylamino-2-oxidoisoquinolin-1-yl Diazomethane: A Novel Water Soluble Fluorescent Labelling Agent for Nucleotides," Chem. Pharm. Bull., 28(6): 1695-1703 (1980) (Exhibit 38);

39. Rosswell, D.F. and White E.H., "The Chemiluminescence of Luminol and Related Hydrazides" in Methods in Enzymol. Vol LV II, Bioluminescence and Chemiluminescnece, DeLuca, M.A. (Ed.) 409-423 (1978) (Exhibit 39);

40. Schott, H., et al., "A Dihydroxyboryl-Substituted Methacrylic Polymer for the Column Chromatographic Separation of Mononucleotides, Oligonucleotides, and Transfer Ribonucleic Acid," Biochemistry 12: 932-937 (1973) (Exhibit 40);

41. Rudkin and Stollar, "High Resolution Detection of DNA-RNA Hybrids in situ by Indirect Immunofluorescence," Nature, 265: 472-73 (1977) (Exhibit 41);

42. Sodja and Davidson, "Gene Mapping and Gene Enrichment by the Avidin-Biotin Interaction: Use of Cytochrome-C as a Polyamine Bridge," Nucl. Acids Res, 5, pp. 385-400 (1978) (Exhibit 42);

43. Voller et al., "Enzyme immunoassays with special reference to ELISA techniques," J. Clinical Pathology, 31: 507-520 (1978) (Exhibit 43);

44. Towbin H. et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications," Proc. Natl. Acad. Sci (USA) 76: 4350-4354 (1979) (Exhibit 44);

45. Weissback, A., and Poonian, M., "Nucleic Acids Attached to Solid Matrices," Methods in Enzymology, Vol. XXXIV, Part B: 463-475 (1974) (Exhibit 45);

46. Van Weemen and Schuurs, "Immunoassay Using Antigen-Enzyme Conjugates," FEBS Letters 15, no. 3: 232-236 (1971) (Exhibit 46);

47. Mathews, J.C. and Cormier, M.J., "Rapid Microassay for the Calcium-Dependent Protein Modulator of Cyclic Nucleotide Phosphodiesterase," Methods in Enzymol. Vol LV II, Bioluminescence and Chemiluminescnece, DeLuca, M.A. (Ed.) 107-108 (1978) (Exhibit 47);

48. Miles Laboratories Inc., GB 1,552,607, published September 19, 1979 (Exhibit 48);

49. Stavrianopoulos et al., Japanese Patent 2,825,090, issued November 18, 1998 (same family as U.S. 4,994,373) (Exhibit 49);

50. UK Patent Application GB 2,125,946, published March 14, 1984 (Exhibit 50);

51. Miles Laboratories Inc., GB-A-1,548,741, published July 18, 1979 (Exhibit 51);

52. Boguslaski et al., UK Patent Application GB-2 045 239 A, published October 29, 1980 (Exhibit 52);

53. Wahl et al., U.S. Patent 4,302,204, issued November 24, 1981 (Exhibit 53);

54. Wagner et al., U.S. Patent 4,166,104, issued August 28, 1979 (Exhibit 54);

55. Wagner et al., U.S. Patent 4,166,103, issued August 28, 1979 (Exhibit 55);

56. Kenoff, U.S. Patent 4,116,638, issued September 26, 1978 (Exhibit 56);

57. Heller, U.S. Patent 4,824,776, issued April 25, 1989 (Exhibit 57);

58. Gutcho et al., U.S. Patent 4,120,945, issued October 17, 1978 (Exhibit 58);

59. Giaever, U.S. Patent 4,041,146, issued August 9, 1977(Exhibit 59);

60. DeLuca-McElroy, U.S. Patent 4,234,681, issued November 18, 1980 (Exhibit 60);

61. UK Patent Application, GB 2 041 922 A, published September 17, 1980 (Exhibit 61);

62. "Diagnostic Immunology: Current and Future Trends," Cap Conference, Aspen,1978, p. 67 and 80 (Exhibit 62);

63. Voller et al., "A microplate method of enzyme-linked immunosorbent assay and its application to malaria," Bull, W.H.O., 51: 209-211 (1974) (Exhibit 63);

64. Szostak et al., "Hybridization with Synthetic Oligonucleotides," Methods in Enzymol. 68: 419-429 (1979) (Exhibit 64);

65. So, et al., "Characterization of an Escherichia coli Plasmid Encoding for the Synthesis of Heat-Labile Toxin: Molecular Cloning of the Toxin Determinant", Infection and Immunity, 21: 405-11(1978) (Exhibit 65);

66. Reiser et al., "Transfer of Small DNA Fragments from Polyacrylamide Gels to Diazobenzyloxymethyl-paper and Detection by Hybridization with DNA Probes," Biochem. And Biophys. Res. Comm., 85, No. 3, pp. 1104-12 (1978) (Exhibit 66);

67. Mesulam, M. M. and Rosene, D.L., "Sensitivity in Horseradish Peroxidase Neurohistochemistry: A Comparative and Quantitative Study of Nine Methods," J. Histochem. Cytochem. 27: No. 3, pp.763-778 (1979) (Exhibit 67);

68. Land, D.B. and Jackim, E., "A New Fluorescence-Yielding Substrate for Alkaline and Acid Phosphatase," Analytical Biochemistry, 16: 481-486 (1966) (Exhibit 68);

69. Kochetkov, N.K. et al., Organic Chemistry of Nucleic Acids, Part B, Kochetkov, N.K., and Budovskii, E.I. (Eds.): 331-332 (1972) (Exhibit 69);

70. Huang and Pagano, "Nucleic Acid Hybridization Technology and Detection of Proviral Genomes," Methods in Virology., 6: 457-97 (1977) (Exhibit 70);

71. Fertel R. and Weiss, B., "Measurement of the Activity of Cyclic Nucleotide Phosphodiesterases with Firefly Luciferin-Luciferase Coupled Assay Systems," Methods in Enzymol. Vol LVII, Bioluminescence and Chemiluminescnece, DeLuca, M.A. (Ed.) 94-96 (1978) (Exhibit 71);

72. Dallas et al. "The Characterization of an Escherichia coli Plasmid Determinant That Encodes for the Production of a Heat-Labile Enterotoxin," Plasmids of Medical Environmental and Commercial Importance, K.N. Timmis and A. Puhler, editors, Elservier/North-Holland Biomedical Press (1979) (Exhibit 72);

73. Bildwell et al., "Enzyme Immunoassays for Viral Diseases," J. Infectious Disease: 136: S274-S278 (1977) (Exhibit 73);

74. Bauman et al., "Rapid and High Resolution Detection of ~~in situ~~ Hybridisation to Polytene Chromosomes Using Fluorochrome-Labeled RNA." ~~Chromosoma (Ber.) 84~~: 1-18 (1981) (Exhibit 74);

75. Broker et al., "Electron Microscopic Visualization of tRNA genes with Ferritin-Avidin: Biotin Labels," ~~Nucl. Acids Res.~~, 5: 363-383 (1978) (Exhibit 75);

76. Engvall and Perlmann, "Enzyme-linked immunosorbent assay (ELISA) Quantitative assay of immunoglobulin G," ~~Immunochem~~ 8: 871-874 (1971) (Exhibit 76);

77. Hofmann et al., "Characterization of the Functional Groups of Bioten", ~~J. Biol. Chem.~~, ~~141~~, 207-11 (1941) (Exhibit 77);

78. ~~Elisa: In The Clinical Microbiology Laboratory~~, ed. T. G. Wreghitt and P. Morgan-Capner, Chapter 1, p. 9, 1990 (Exhibit 78); and

79. Dallas and Falkow, "Molecular and Genetic Analysis of a DNA sequence Encoding for Enterotoxin Synthesis in ~~Escherichia coli~~," ~~Thirteenth Joint Conference on Cholera~~, The U.S. – Japan Cooperative Medical Science Program (1979) (Exhibit 79).

Copies of the above-listed 79 documents are being submitted herewith as Exhibits 1-79. A completed Form PTO-1449 is also attached as Exhibit 80.

Of the above-listed 79 documents, nos.1-3 (Exhibits 1-3) were part of 47 documents which were previously submitted in a June 2, 1994 IDS filed in the parent application, Serial No. 07/967,676 (filed on October 28, 1992). Those 47 documents were also listed on a Form PTO-1449 submitted with that June 2, 1994 IDS. Nos. 1-3 (Exhibits 1-3) were crossed off by the Examiner on a return July 22, 1994 Form PTO-1449 (Exhibit 81) and later attached to a July 25, 1994 Office Action. Thus, it appears that nos. 1-3 (Exhibits 1-3) were never considered by the Examiner.

Because Applicants have no record that document nos. 1-3 (Exhibits 1-3) were ever considered by the Examiner, Applicants are submitting herewith these 3 documents as Exhibits 1-3.

With respect to U.S. Patent No. 4,724,202, issued February 9, 1998 (Exhibit 4), this document was raised in Applicants' September 2, 1994 Amendment also filed in the parent application, Serial No. 07/967,646.

Document Nos. 5-7 (Exhibits 5-7) were cited in the present application in the Supplemental Declaration of Dr. Dean L. Engelhardt submitted in Applicants'

S ptember 21, 1998 Supplemental Response. These three documents include Buongiorno-Nardelli and Amaldi, "Autoradiographic Detection of Molecular Hybrids between rRNA and DNA in Tissue Sections," Nature 225: 946-948 (Exhibit 5); Gall and Pardue, "Formation and Detection of RNA-DNA Hybrid Molecules in Cytological Preparations," Genetics 63: 378-383 (Exhibit 6); and John et al., "RNA-DNA Hybrids at the Cytological Level," Nature 223: 582-587 (1969) (Exhibit 7).

Document Nos. 8-10 (Exhibits 8-10) were cited in a May 14, 1996 Amendment filed in the present application. These three documents include Ward et al., U.S. Patent No. 5,328,824, issued July 12, 1994 (Exhibit 8); Ward et al., U.S. Patent No. 5,449,767, issued September 12, 1995 (Exhibit 9); and Engelhardt et al., U.S. Patent No. 5,260,433, issued November 9, 1993 (Exhibit 10).

The remaining documents, nos. 11-79 (Exhibits 11-79), were cited in various European prosecutions, proceedings or oppositions involving the foreign counterpart or counterpart divisional application.

Four other documents (Exhibits 2, 24, 51 and 81) deserve additional mention. The English equivalent to DE-A-29 15 082, published October 31, 1979 (Exhibit 2) is believed to be Kourilsky et al., U.S. Patent No. 4,581,333, issued April 8, 1986. Kourilsky was previously considered by the Examiner (see the July 22, 1994 return Form-1449 attached as Exhibit 81). The English equivalent to DE-A-2618419, published April 11, 1976 (Exhibit 24), is believed to be GB 154 87 41 (Exhibit 51). Because the remaining documents listed on attached Form PTO-1449 are in English, no further commentary is believed to be required under 37 C.F.R. §198(a)(3).

By this voluntary citation of art, Applicants and their attorney are requesting that these 79 documents (Exhibits 1-79) be made of record in the present application.

The above listing is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant references, nor are these documents necessarily a complete listing of all references known to Applicants or their attorneys. It is simply a voluntary citation of references made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own searches.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither suggested nor disclosed by the documents listed above and, thus, patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these documents, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under any of the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents (Exhibits 1-79) of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate, however remotely, to the present application.

This IDS is being filed in accordance with 37 C.F.R. §1.97(c), that is, after the mailing date of a first action on the merits, but before the mailing date of either a Final Action or a Notice of Allowance. The Patent and Trademark Office is hereby authorized to charge the $240.00 fee set forth in §1.17(p) and any other fees in connection with this IDS to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,

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